



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,973	02/26/2002	James S. Norris	14017-004002 /PSU 96-1566	8113
26161 7590 09/19/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER EPPS FORD, JANET L	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 09/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/082,973	Applicant(s) NORRIS ET AL.	
	Examiner Janet L. Epps-Ford	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 39-55 are presently pending.

#### *Response to Arguments*

#### *Claim Rejections - 35 USC § 112*

3. Claims 39-55 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter/Written description).
4. Applicant's arguments filed 6-26-07 have been fully considered but they are not persuasive. Applicants have amended the instant claims to recite wherein the sum of the number of nucleotides of said first and second arms is from 25 nucleotides to 53 nucleotides. As support for their amendment Applicants make reference to the specification at page 36, lines 4-8, and Figure 3. Page 36, lines 4-8, recite:

- 5 catalytic activity as well. This invention includes modifications to and use of the ribozyme described in U.S. Serial No. 08/554,369 and PCT publication No. WO98/24925, which are incorporated by reference herein in their entirety.

The ribozymes of the present invention have several important modifications. The arms of the cis-acting ribozymes have been lengthened by 20 bases. The sequence has been

However, Applicant's reference to this passage is improper to provide support for the newly added limitations to the claims. As per 37 CFR § 1.57(c) "[E]ssential material "

Art Unit: 1633

may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference.

"Essential material " is material that is necessary to:

- (1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;
- (2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or
- (3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112.

In the instant case, it appears that Applicants are relying upon the disclosure of an international publication to provide evidence of written description of the claimed invention.

The specification as filed, as referred to by Applicants in their support for the instant amendment provides only two examples, particularly Figure 3, wherein the 18:7 3' cis-acting ribozyme comprises a first and second arm totaling 25 nucleotides, and the 7:20 5' cis-acting ribozyme comprising arms totaling 27 nucleotides. However, other than these two examples, there is no support for ribozyme constructs of the present invention. Applicants amendment therefore is considered new matter since there is lack of sufficient antecedent basis for the newly added limitation of "wherein the sum of the number of nucleotides of said first and second arms is from 25 nucleotides to 53," recited in the instant claims. Applicants are requested to remove the new matter in response to this Action.

Moreover, in regards to the rejection of claims 40-41, Applicants argue "[A]pplicants' specification adequately describes structures for a pCHOP and a pSNIP cassette. A structure of a pCHOP cassette is set forth in Figure 3, and in Figure 4 as part of a pSNIP cassette. A structure of a pSNIP cassette is set fort in Figure 4. Thus, Applicants' specification fulfills the requirement for written description of a pCHOP cassette and a pSNIP cassette." It is noted that Applicants do not state that the structures set forth in Figures 3 and 4 represent the only possible structures for the claims pCHOP and pSnip cassettes, Applicants state that these figures describe a structure of a pChop cassette, or a structure of a pSnip cassette. Since the instant claims are not limited to these particular structures, it is unclear what other structures may be included within the scope of the instant claims. Moreover, in the instant case, Applicants have not disclosed any particular correlation between the function of the "pChop" cassette or "pSnip" cassette according to the present invention and their corresponding structure, such that the skilled artisan would be able to immediately envision and predict the structures of other nucleic acid sequences encoding these constructs. *See MPEP § 2163, which states, "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."*

***Claim Rejections - 35 USC § 101***

5. The rejection of claim 53 under 35 USC §101 is withdrawn in response to Applicant's amendment filed 6-26-07.

***Claim Rejections - 35 USC § 102***

6. Claims 39-40, and 42-55 remain rejected under 35 U.S.C. 102(a) as being anticipated by Norris et al. (WO98/24,925), for the reasons of record.

7. Applicant's arguments filed 6-26-07 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the declarations filed under 37 CFR § 1.131 demonstrate Applicant's prior completion of multiple species, which put Applicants in possession of the claimed invention.

8. The Rule § 1.131 filed on 6-26-07 under 37 CFR 1.131 has been considered but is ineffective to overcome the Norris et al. reference. It is noted that only a total of six out of nine inventors of the instant application signed the Rule § 1.131 declaration filed 6-26-07. As per MPEP § 715.04 [R-5] :

The following parties may make an affidavit or declaration under 37 CFR 1.131:

(A) ***All the inventors of the subject matter claimed.***

(B) An affidavit or declaration by less than all named inventors of an application is accepted where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection. For example, one of two joint inventors is accepted where it is shown that one of the joint inventors is the sole inventor of the claim or claims under rejection. A Declaration signed only by a single inventor is not sufficient to make affidavit or declaration.

Art Unit: 1633

(C) If a petition under 37 CFR 1.47 was granted or the application was accepted under 37 CFR 1.42 or 1.43, the affidavit or declaration may be signed by the 37 CFR 1.47 applicant or the legal representative, where appropriate.

(D) The assignee or other party in interest when it is not possible to produce the affidavit or declaration of the inventor. Ex parte Foster, 1903 C.D. 213, 105 O.G. 261 (Comm'r Pat. 1903).

Affidavits or declarations to overcome a rejection of a claim or claims must be made by the inventor or inventors of the subject matter of the rejected claim(s), a party qualified under 37 CFR 1.42, 1.43, or 1.47, or the assignee or other party in interest when it is not possible to produce the affidavit or declaration of the inventor(s). Thus, where all of the named inventors of a pending application are not inventors of every claim of the application, any affidavit under 37 CFR 1.131 could be signed by only the inventor(s) of the subject matter of the rejected claims.

Norris et al. teach nucleic acid molecules comprising tissue-specific and pathogen-specific promoters positioned upstream from a sequence from a sequence encoding ribozymes comprising a 5' autocatalytically cleaving ribozyme sequence, a catalytic ribozyme comprising a target RNA-specific binding site and a 3' autocatalytically cleaving ribozyme sequence. The Norris et al. reference further teaches wherein said catalytic ribozymes target rpoA, secA, ftsZ and dnaG RNA transcripts. This reference further teaches vectors comprising said nucleic acid molecules and those comprising multiple ribozyme structures, virions comprising said nucleic acid molecules, liposomes comprising said nucleic acid sequence, and methods

Art Unit: 1633

for both treating and delivering said nucleic acid into cells. A specific example of a ribozyme construct disclosed by Applicants includes a construct against the *secA* gene inserted into the pClip vector (P. 44).

Additionally, Norris et al. teach lengthening the arms of the cis-acting ribozymes by 20 bases, this modification is disclosed as functioning to enhance the catalytic activity of the cis-acting elements (see page 21, last paragraph). See also Figures 5 and 6 wherein the arms of the cis-acting ribozymes are 25 nucleotides or more.

Norris et al. teach each and every aspect of the instant invention thereby anticipating applicant's claimed invention.

### **Conclusion**

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



Art Unit: 1633

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner  
Art Unit 1633

JLE